

SENATE, No. 2364

STATE OF NEW JERSEY 212th LEGISLATURE

INTRODUCED DECEMBER 4, 2006

Sponsored by:

Senator LEONARD LANCE

District 23 (Warren and Hunterdon)

Senator RICHARD J. CODEY

District 27 (Essex)

Co-Sponsored by:

Senators T.Kean and Karcher

SYNOPSIS

Requires physicians and other prescribers to obtain informed consent from parents or guardians of minors for medications with “black box warnings.”

CURRENT VERSION OF TEXT

As introduced.



(Sponsorship Updated As Of: 1/30/2007)

1 AN ACT concerning the prescribing of certain medications to
2 individuals under 18 years of age, and supplementing Title 45 of
3 the Revised Statutes.

4
5 **BE IT ENACTED** *by the Senate and General Assembly of the State*
6 *of New Jersey:*

7
8 1. Prior to prescribing for an individual under 18 years of age
9 any medication required by the federal Food and Drug
10 Administration to have a “black box warning” on its labeling, a
11 physician or other authorized prescriber shall inform the
12 individual’s parent or legal guardian about the possible side effects
13 of the medication and shall obtain informed consent from the
14 individual’s parent or legal guardian for the notification.

15 A physician or other authorized prescriber who prescribes a
16 medication in violation of this act shall be subject to disciplinary
17 action by the State Board of Medical Examiners.

18
19 2. Prior to prescribing for an individual under 18 years of age
20 any medication required by the federal Food and Drug
21 Administration to have a “black box warning” on its labeling, an
22 advanced practice nurse shall inform the individual’s parent or legal
23 guardian about the possible side effects of the medication and shall
24 obtain informed consent from the individual’s parent or legal
25 guardian for the notification.

26 An advanced practice nurse who prescribes a medication in
27 violation of this act shall be subject to disciplinary action by the
28 New Jersey Board of Nursing.

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30 3. The Division of Consumer Affairs in the Department of Law
31 and Public Safety, in consultation with the Department of Health
32 and Senior Services, shall adopt, pursuant to the "Administrative
33 Procedure Act," P.L.1968 c.410 (C.52:14B-1 et seq.), rules and
34 regulations necessary to implement the provisions of this act.

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36 4. This act shall take effect 180 days after enactment.

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39 STATEMENT

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41 This bill requires physicians, advanced practice nurses, and other
42 authorized prescribers to obtain informed consent from parents or
43 legal guardians of minors prior to prescribing them medications that
44 are accompanied by a “black box warning.”

45 The United States Food and Drug Administration (FDA) requires
46 pharmaceutical companies to place a “black box warning” on a drug
47 label if medical studies indicate that the drug carries a significant

1 risk of serious or life-threatening adverse effects. A “black box
2 warning” is the strongest warning that the FDA requires.

3 Pursuant to the bill, a physician, advanced practice nurse, or
4 other authorized prescriber in violation of the bill is to be subject to
5 disciplinary action by the applicable State professional licensing
6 board.